

wild-type protein expressed by one of the subject genes in said sample is about 50%  $\pm$  10% of the level of said wild-type protein in comparable samples from organisms unaffected by said disease or said disease susceptibility trait.

58. The method of Claim 35 wherein said cells are peripheral blood lymphocytes.

b1 59. The method of Claim 40 wherein the normal biological sample comprises peripheral blood lymphocytes.

60. The method of Claim 42 wherein the normal biological sample comprises peripheral blood lymphocytes.

---

#### REMARKS

As required by 37 CFR 1.121(c)(3), enclosed herewith as Appendix 1 is a clean set of all the claims now pending.

Applicant has cancelled the claims of the non-elected Group I of the restriction requirement - i.e., Claims 1-6, 9-23 and 45-53. New Claims 55-60 have been added.

Support for the new claims can be found throughout the Specification. Support for the new Claims 55-57 can be found in Claims 54 and in the application at least at page 5, line 24 to

page 6, line 20; at page 9, line 22 to page 10, line 2; at page 11, lines 19-21; at page 19, line 27 to page 20, line 3; at page 45, lines 24-29; at page 49, lines 1-25; and at page 50, lines 1-5. Specifically the ranges of Claims 55-57 can be found at page 9, line 32 to page 10, line 2.

Support for Claims 58-60 can be found at least at page 12, lines 7-10 which read that "[f]urther preferred" biological samples are:

normal cell samples, normal cell extracts, lysates of normal cells, and supernatants of normal cell lysates. Particularly preferred are samples of peripheral blood lymphocytes (PBLs), lysates of PBLs, supernatants from lysates of PBLs, and extracts of PBLs.

[Emphasis added.]

Applicant respectfully concludes that no new matter has been entered by the above amendment.

#### ELECTION

Applicant respectfully elects the Group II claims - Claims 24-28, 31-44 and 54 - with traverse. Applicant reserves the right under 35 USC Section 121 to file subsequent divisional application(s) to protect the invention commensurate with the scope as originally filed.

The Examiner contends that Group II contains claims directed to "a plurality of patentably distinct species of

subject genes", and states that "Applicant is required under 35 U.S.C. Section 121 to two disclosed species . . ." [Office Action, page 4.] In response, Applicant respectfully points out that claims of the type submitted herein are proper in accordance with the decision in the case of In re Harnisch, 206 USPQ 300 (CCPA 1980) concerning Markush claims.

Applicants respectfully points out that the examination of Markush claims is governed by Section 803 of the Manual of Patent Examining Procedure (MPEP), which provides an exception to the normal practice of requiring restriction or election. That section, which is based on a series of decisions from the Court of Customs and Patent Appeals (CCPA)<sup>1</sup> culminating in In re Harnisch, id., specifically states that in many cases Markush claims do include inventions which would otherwise be considered independent and distinct [MPEP Section 803.02]. Thus, Applicant respectfully has no comment as to whether the various species encompassed by the claims are patentably distinct, and respectfully submits that Applicant need not make any such comment.

---


1. The CCPA is a predecessor court to the Court of Appeals for the Federal Circuit. In the Federal Circuit's first reported opinion, South Corp. v. United States, 215 USPQ 657 (Fed. Cir. 1982), the Federal Circuit adopted as binding precedent "the holdings of our predecessor courts, the United States Court of Claims and the United States Court of Customs and Patent Appeals [CCPA]. . . ."

Applicant respectfully considers the requirement for election of a two disclosed species as one made for commencement of examination pursuant to MPEP Section 803. Thus, for the purposes of commencing examination of the instant application, Applicant provisionally elects the MLH1 and MSH2 genes.

CONCLUSION

Applicant respectfully concludes that the claims as amended are in condition for allowance, and earnestly requests that the claims be promptly allowed. If for any reason Examiner feels that a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to telephone the undersigned Attorney for Applicant at (415) 981-2034.

Respectfully submitted

  
Leona L. Lauder  
Attorney for Applicant  
Registration No. 30,863

Dated: August 15, 2001